

Application No.: 09/965610

Case No.: 56032US022

Amendments to the Claims:

The following Listing of Claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

1. (Previously presented) A transdermal drug delivery composition consisting essentially of
 - (a) a copolymer comprising
 - (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
 - (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and
 - (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;wherein the composition is substantially free of undissolved fentanyl.
2. (Original) The composition of claim 1 wherein the A monomer is selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate.
3. (Original) The composition of claim 1 wherein the A monomer is isooctyl acrylate.
4. (Original) The composition of claim 1 wherein the B monomer is selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof.
5. (Original) The composition of claim 1 wherein the B monomer is 2-hydroxyethyl acrylate.

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6. (Original) The composition of claim 5 wherein the copolymer comprises from about 5% to about 45% of 2-hydroxyethyl acrylate by weight based on the total weight of all monomers in the copolymer.
7. (Original) The composition of claim 1 wherein the copolymer further comprises a macromonomer.
8. (Original) The composition of claim 7 wherein the macromonomer is a functionally terminated polymethylmethacrylate.
9. (Original) The composition of claim 7 wherein the copolymer contains from about 1% to about 6% of macromonomer by weight based on the total weight of all monomers in the copolymer.
10. (Canceled).
11. (Canceled).
12. (Canceled).
13. (Canceled).
14. (Canceled).
15. (Canceled).
16. (Original) The composition of claim 1 wherein the concentration of fentanyl in said transdermal drug delivery composition is from about 12% to about 24% by weight.

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17. (Original) The composition of claim 7 wherein the copolymer comprises from about 50 to about 94% isooctyl acrylate, about 5% to about 40% 2-hydroxyethyl acrylate, about 1% to about 6% macromonomer, and 0% to about 20% vinyl acetate by weight.
18. (Original) The composition of claim 7 wherein the copolymer comprises from about 52% to about 60% isooctyl acrylate, about 35% to about 40% 2-hydroxyethyl acrylate, about 1% to about 4% macromonomer, and 0% to about 10% vinyl acetate by weight.
19. (Canceled).
20. (Canceled).
21. (Canceled).
22. (Canceled).
23. (Canceled).
24. (Canceled).
25. (Canceled).
26. (Canceled).
27. (Canceled).
28. (Original) A method of treating in a mammal a condition capable of treatment by fentanyl comprising the steps of:
 - (a) providing a composition according to claim 1;
 - (b) placing the composition on the skin of a mammal; and

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- (c) allowing the composition to remain on the skin for a time sufficient to establish or maintain a therapeutically effective blood level of fentanyl in the mammal.
29. (Original) A method of providing analgesia to a mammal comprising the steps of:
- (a) providing a composition according to claim 1;
 - (b) placing the composition on the skin of a mammal; and
 - (c) allowing the composition to remain on the skin for a time sufficient to establish or maintain an analgesically effective blood level of fentanyl in the mammal.
30. (Previously presented) A method of providing sustained analgesia to a mammal comprising delivering fentanyl to a mammal via a transdermal drug delivery device in an amount of about 0.5 to about 5.0 mg/day thereby causing the serum concentration of fentanyl in the mammal to be about 0.2 to about 10 ng/mL for a period of time from about 4 to about 14 days, wherein the device includes a composition ~~comprising an acrylate polymer and about 8% to about 30% by weight fentanyl based on the total weight of the composition, wherein the composition is substantially free of undissolved fentanyl~~ according to claim 1.
31. (Original) The method of claim 30 wherein the fentanyl is delivered in an amount of 0.5 to 2.5 mg/day, the serum concentration of fentanyl in the mammal is about 0.3 to about 4 ng/mL, and the period of time is from about 6 to about 8 days.
32. (Canceled).
33. (Canceled).
34. (Canceled).
35. (Previously presented) A transdermal drug delivery composition ~~comprising~~ consisting of:

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(a) a copolymer comprising:

- (i) one or more A monomers from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
- (ii) one or more ethylenically unsaturated B monomers copolymerizable with the acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxythyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

36. (Previously presented) A transdermal drug delivery composition ~~comprising~~ consisting of:

(a) a copolymer comprising:

- (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
- (ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N, N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl.

37. (Previously presented) A transdermal drug delivery composition ~~comprising~~ consisting of:

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(a) a copolymer comprising

- (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
- (ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer, wherein at least one B monomer is 2-hydroxyethyl acrylate; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is substantially free of undissolved fentanyl; and
wherein the drug delivery device delivers fentanyl to a mammal via a transdermal drug delivery device in an amount of about 0.5 to about 5.0 mg/day thereby causing the serum concentration of fentanyl in the mammal to be about 0.2 to about 1.0 ng/mL for a period of time from about 4 to about 14 days.

38. (Canceled).